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(54) Title: PERSONAL NUTRITION CONTROL METHOD

(57) Abstract: There is provided a method and a system for monitoring or controlling and recording a nutritional intake of a subject comprising providing a plurality of different types of foods packaged to contain a predetermined and substantially uniform content of at least one nutritional component; and monitoring or controlling the number of food packages consumed during a predetermined time period. There is also provided a food unit and an assembly of food units for use in effecting the method and the system.

PERSONAL NUTRITION CONTROL METHOD

FIELD AND BACKGROUND OF THE INVENTION

5 The present invention relates to the field of diet control systems and more particularly to a highly flexible, personally directed food consumption method designed to allow a subject to plan, monitor, control, document, record and learn the appropriate nutritional intake.

10 One of the most prevalent health problems in the Western World and especially in the United States is that of excessive body weight. Being overweight is epidemic, with more than 50 percent of the adult population of the U. S. suffering therefrom.

Accordingly, developing and maintaining a physically fit and healthy body is becoming the goal of an increasing number of individuals. As of late, the public has become increasingly aware of the importance of a proper diet for weight control as well as for health maintenance and disease prevention. As a result, many diets have been designed to lose weight, to maintain present weight, or to assure the consumption of appropriate nutrition.

20 A large segment of the population is on a special diet at any given time. According to the American Obesity Association, it is estimated that 40% of the women and 25% of the men of the United States are on a special diet for the purpose of weight control. Unfortunately, most dieters fail to achieve their goals for a number of reasons. First, many diets have numerous different and often conflicting guidelines that are presented in a complex manner so that it is often difficult for a person to understand and carry out the diet correctly. A second reason is the often sparse, rigid or monotonous nature of the nutritional regimen prescribed. Self-deprivation is not a well developed trait in modern society. A third reason is that most diets do not address the need for the dieter to understand the underlying principles of the diet so that he/she can effectively maintain personally appropriate eating habits after the diet period has ended.

The bottom line with respect to all weight control diets is the need to limit calories. With very few exceptions (such as, for example, serious illnesses), the only way by which a person loses weight is by consuming less calories than is required by the body metabolism to support the required energy level. When fewer calories are consumed, the body metabolizes stored body fat, resulting in weight loss. Conversely, when too many calories are consumed, the body stores this excess energy source as body fat, resulting in weight gain.

It will be appreciated that the above description is somewhat simplified. Not only are calories important, it is also important to obtain the calories from foods that provide proper nutrition to the body. The body has a broad range of nutritional needs in order to maintain health and full function. Accordingly, a person who simply counts calories will not achieve the goal of developing and maintaining a physically fit and healthy body since being concerned with calories to the exclusion of all other factors will not provide proper nutrition.

It is known that a balanced diet includes food from several food groups in order to provide optimum levels of nutrients such as protein, carbohydrates, fats, fiber vitamins and minerals.

Accordingly, the prior art teaches many meal planning aids to assist dieters to consume a diet with proper macro and micronutrient balance. One such aid is disclosed in U.S. Patent No. 3,681,857 to Yardley which consists of a device which includes preprinted strips attached to a board which indicate the quantity of the different food items consumed and their nutrient value. Another is disclosed in U.S. Patent No. 4,310,316 to Thomann which is a diet control device consisting of tickets, vouchers and containers, color coded according to lists of foods and categories of foods. Further prior art diet aids include those disclosed in U.S. Patent No. 4,652,241 to McCarty which employs a device with movable members in display zones representing predefined food groups and portions; and in U.S. Patent No. 4,606,555 to Adams which uses a set of booklets and cards as a diet control device.

Although considerable effort is represented by the prior art with regard to administering dietary meal plans, the results have not been totally satisfactory due to the need for ongoing record keeping and oversight, and in most cases the procedures involved are cumbersome, time consuming, and inconvenient to carry out.

Another well-known diet management system, known generally as an "exchange diet", divides food into six groups or "exchanges." The original exchange diet, developed for diabetics and now used by anyone wishing to control or lose weight, is more specifically discussed in the booklet entitled "Exchange List For Meal Planning," prepared by the American Diabetes Association, Inc. and the American Dietetic Association. According to such exchange diets, food groups are referred to as exchanges, such as bread exchanges, meat exchanges, fat exchanges, fruit exchanges, milk exchanges, and vegetable exchanges. The "exchange" is a unit of food which may be different for each food group. However, within a particular food group each exchange is approximately equal in calories and in the amount of certain nutrients such as carbohydrates, proteins, fats, fiber minerals and vitamins. For each food group, an "exchange list" is provided which sets forth the amount of a specific food that constitutes an exchange. For example, in the above-identified booklet, a small apple and one-fourth of a cantaloupe melon is one fruit exchange.

The exchange diet further specifies the number of exchanges for each food group for a specified daily caloric intake. For example, for a daily two thousand calorie intake, a person is allowed nine bread exchanges, nine meat exchanges, four fat exchanges, six fruit exchanges, three milk exchanges, and two vegetable exchanges.

As can be seen, exchange diets require time and careful attention to carry out properly. A person observing an exchange diet must (a) determine the number of exchanges allowed for each food group, (b) keep track of the number of exchanges consumed in each food group, and (c) keep track of the

number of exchanges remaining in each food group. Such information is typically processed and maintained by memory, by notes, or by predetermined menus. Experience has shown that these procedures are both time-consuming and prone to error.

5 In order to address this deficiency of exchange diets, aids have been developed to assist the dieter. One such aid is the mechanized management system disclosed in U.S. Patent No. 3,841,260 to Sharp. The system includes a sheet with an array of holes aligned in columns and rows representing the six different food groups. Color coded pegs, representing one exchange for the
10 food group identified by the color of the peg, are inserted into the holes at appropriate locations. The system includes listings of foods in each food group and the number of exchanges permitted for each group for certain calorie intake limits. This system appears to be bulky and not readily carried by the user.

Another device to assist with the implementation of exchange diets is
15 disclosed in U.S. Patent No. 4, 625,675 to Rosenberg which is a hand-held and portable manipulatable device with a housing, slide members, a numerical display and card inserts. A further attempt is disclosed in U.S. Patent No. 4,689,019 to Tilney which is a meal planning kit for adhering to a predetermined diet, primarily for diabetics. The kit contains color coordinated
20 cards to match food groups, and self adhesive stickers for affixing to the cards.

While the above described devices and systems provide for orderly and systematic monitoring of exchange limits and exchanges consumed, they are all awkward and cumbersome to use on a daily basis.

A further well-known method of managing a diet consists of
25 preprepared and prepackaged dietetic food. Indeed, supermarket shelves and freezers are full of such foods. Such dietetic food is often prepackaged into meals that provide well balanced nutrition with limited calories. However, they do not provide any guidance to the dieter for building nor adhering to a structured diet. Moreover, nothing prevents a hungry dieter from eating half a
30 dozen of such meals each day or, for that matter, at a sitting.

Attempts have been made to structure a system of prepackaged meals into an ongoing diet. U.S. Patent No. 6,039,989 to Bangs provides a system of prepackaged meals for treatment of diet-responsive conditions and U.S. Patent No. 6,102,706 to Khoo discloses a compliance support system consisting principally of prepackaged meals. As these systems demonstrate, the problem of planning and maintaining a healthful diet goes beyond weight control concerns and exists with respect to other special diets such as those associated with diet-responsive health conditions like cardiovascular disease, diabetes, hypercholesterolemia, hyperglycemia, osteoporosis, cancer and many others, and those required for individuals with special sensitivities or allergies or individuals requiring a special diet such as athletes.

There are some advantages to such systems, as the variety of foods within the prepackaged meals enhances ongoing compliance with the diet and there is very little preparation or cooking to do. However, such meals and such systems that utilize such meals have a number of disadvantages, such as denying the dieter the option of selecting the components of each meal, not providing the dieter with the tools nor the knowledge to understand what he/she is consuming, not facilitating the dieter's ability to carry on healthy eating habits after ending the diet, and not providing any means for monitoring or oversight of compliance.

There is thus a widely recognized need for, and it would be highly advantageous to have, a nutrition control system that does not suffer the above described drawbacks.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a nutrition consumption planning and control system which is easy to use and does not require an individual to identify and calculate the calories in any particular food being consumed.

It is a further object of the present invention to provide a nutrition consumption planning and control system which is highly flexible and allows an individual to vary the foods being eaten for any meal, while still maintaining the desired caloric intake.

5 According to one aspect of the present invention there is provided a method of monitoring or controlling a nutritional intake of a subject comprising: (a) providing a plurality of food packages containing a plurality of different types of foods, each having a predetermined and substantially uniform content of at least one nutritional component; and (b) monitoring or controlling
10 the food packages consumed by the subject per eating session or per a predetermined time period; thereby monitoring or controlling the nutritional intake of the subject.

 According to another aspect of the present invention there is provided a food unit comprising: (a) a package; (b) a type of food packaged in the package
15 having a predetermined content of at least one nutritional component; and (c) an indication in print on or in the package indicating: (i) the predetermined content of the nutritional component; and (ii) an availability of other food units having the predetermined content of at least one nutritional component.

 According to yet another aspect of the present invention there is
20 provided a food unit comprising: (a) a package; (b) a type of food packaged in the package and having a predetermined content of at least one nutritional component; and (c) a removably affixable label on or in the package indicating thereon the predetermined content of the nutritional component.

 According to yet another aspect of the present invention there is
25 provided a system for monitoring or controlling a nutritional intake of a subject, the system comprising (a) at least one package; (b) a type of food packaged in the package and having a predetermined content of at least one nutritional component, the package having therein or thereon information about the predetermined content of the nutritional component; and (c) a marker which
30 provides information about at least one nutritional component; (d) a recording

device for recording the information about the predetermined content of the nutritional component, such that the information on the package may be recorded in the recording device, thereby to monitor or control a nutritional intake of a subject.

5 According to yet another aspect of the present invention there is provided an assembly of food units comprising a plurality of food units, each food unit comprising: (a) a package; and (b) a different type of food packaged in the package and having a predetermined content of at least one nutritional component which is substantially uniform for all of the food units of the
10 assembly of food units.

 According to features in the described preferred embodiments each of the food packages is identified with respect to a type of food it contains.

 According to features in the described preferred embodiments each of the food packages is identified with respect to a content of the nutritional
15 component it contains.

 According to features in the described preferred embodiments each of the food packages contains an indication of the availability of a plurality of different types of foods having the predetermined content of at least one nutritional component.

20 According to features in the described preferred embodiments each of the food packages contains an indication of the method.

 According to features in the described preferred embodiments at least one nutritional component is selected from the group consisting of carbohydrates, sugars, fats, fiber, cholesterol, proteins, amino acids, minerals
25 and vitamins.

 According to features in the described preferred embodiments at least one nutritional component is calorie content.

 According to features in the described preferred embodiments the calorie content is selected from the group consisting of about 50 calories, about
30 75 calories, about 100 calories, about 125 calories, about 150 calories, about

175 calories, about 200 calories, about 225 calories, about 250 calories, about 275 calories and about 300 calories.

As used herein the term "about" refers to $\pm 10\%$.

According to features in the described preferred embodiments the
5 calorie content is about 100 calories.

According to features in the described preferred embodiments the subject has a diet-responsive condition.

According to features in the described preferred embodiments the diet-responsive condition is selected from the group consisting of obesity,
10 overweight, diabetes, hypercholesterolemia and hyperglycemia.

According to features in the described preferred embodiments the foods are selected from the group consisting of natural foods, processed foods and drinks.

According to features in the described preferred embodiments the foods
15 are processed to extend shelf life.

According to features in the described preferred embodiments each of the packages is marked in a specific manner that identifies it with an assembly which comprises similarly marked packages.

According to features in the described preferred embodiments each of
20 the food packages contains a marker which provides information about at least one nutritional component.

According to features in the described preferred embodiments the marker is a removably affixable label.

According to features in the described preferred embodiments the
25 method further comprises recording the information about the nutritional component in a recording device.

According to features in the described preferred embodiments the recording device is a diary or a calendar, the marker being affixable thereto.

According to features in the described preferred embodiments the
30 subject participates in a nutritional research.

According to features in the described preferred embodiments the plurality of food packages is prepackaged in a container.

According to features in the described preferred embodiments the plurality of food packages is displayed on a display.

5 According to features in the described preferred embodiments the time period is one day.

According to features in the described preferred embodiments the indication further indicates a method of monitoring or controlling a nutritional intake of a subject via monitoring or controlling a number of food units
10 consumed by the subject per eating session or per a predetermined time period.

According to features in the described preferred embodiments the type of food is for consumption by a subject seeking to control calorie intake.

According to features in the described preferred embodiments the type of food is for consumption by a subject having a diet-responsive condition.

15 According to features in the described preferred embodiments the indication is located on a marker removably affixed to the package.

The present invention successfully addresses the shortcomings of the presently known configurations by providing a nutrition consumption planning and control system which is easy to use and does not require an individual to
20 identify and calculate the calories in any particular food being consumed, which requires a subject to simply count the number of packages of food eaten in order to adhere to a predetermined caloric intake, and which is highly flexible and allows an individual to vary the foods being eaten for any meal, while still maintaining the desired caloric intake.

25

BRIEF DESCRIPTION OF THE DRAWINGS

With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for the purposes of illustrative discussion of the preferred embodiment of the present invention
30 only, and are presented in the cause of providing what is believed to be the

most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail that is necessary for a fundamental understanding of the invention, the description taken with the drawings making
5 apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 is a flowchart in accordance with the method of the present invention;

10 FIG. 2 is a perspective diagram illustrating a food package constructed in accordance with the present invention;

FIG. 3 is an illustration of a marker of the food package of FIG. 2; and

FIG. 4 is a perspective diagram illustrating a recording device constructed in accordance with the present invention;

15 FIGs. 5a-b are perspective diagrams illustrating assemblies of the food packages of FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a method of planning, controlling and
20 monitoring nutrition consumption which is highly flexible and allows an individual to vary the foods being eaten without having to measure the quantities of the foods and calculate the calories therein. The present invention is further of prepackaged food items designed for implementing the method.

The principles and operation of a method of monitoring or controlling a
25 nutritional intake of a subject according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in this application to the details of construction and the arrangement of the components set forth in the
30 following description or illustrated in the drawings. The invention is applicable

to other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

In its broad sense, the present invention is of a method that includes of
5 packaging and labeling food according to unit quantities of nutrient content, specifically but not exclusively caloric content, in order to adhere to a predetermined regimen of personal daily nutrition, to facilitate the consumption of a predetermined quantity of a specific nutrient or to monitor the intake of a specific nutrient.

10 As used herein, the term "food" refers to any natural, processed or otherwise produced solid or liquid comestible that is customarily eaten for the purpose of introducing digestible or non-digestible material into the gastro-intestinal tract.

As used herein, the term "nutritional component" refers to
15 macronutrients, micronutrients, non-digestible materials and any other quantifiable component, element or characteristic of a comestible substance, including, but not limited to, calories, carbohydrates, sugars, fats, saturated fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

As used herein, the term "personal daily nutrition" refers to the content
20 and quantity of food, apportioned and packaged into single portions having a predetermined and substantially uniform nutritional component value, that is consumed in a predetermined time period, preferably one day.

Thus, according to the present invention, and as illustrated in Figures
1-5, there is provided a method of monitoring or controlling a nutritional intake
25 of a subject which is referred to herein as method 10.

Reference is now made to Fig. 1 which shows a flow chart illustrating
method 10, showing a process with a minimum of two steps. The first step,
referred to hereinafter as providing step 11, consists of providing a plurality of
food packages containing a wide variety of different types of food, each having
30 a predetermined and substantially uniform content of at least one nutritional

component, to a subject. The second step, referred to hereinafter as monitoring step 12, consists of monitoring or controlling the number of food packages consumed by the subject in a predetermined time period, preferably one day.

Reference is now made to Fig. 2 which shows a package for packaging food in accordance with the teachings of the present invention, hereinafter referred to as package 13. Package 13 is shown in a simplified form representative of the packaging appropriate for the type of food that may be packaged for use as part of method 10. It is understood that package 13 may be any type of package, made of any material, in which comestible substances are or may be enclosed for storage until eaten. The alternatives of material, design and configuration of package 13 are vast, consistent with current and future packaging technology and practices for the very wide scope of foods that may be packaged therein.

The range of foods, both natural and processed, that may be packaged in package 13 is extremely varied and broad and may include natural and processed foods from all commonly existing food groups, such as bread, baked goods, grains, pasta, rice; vegetables; fruits; milk products, liquid and solid; high protein products such as meat, fish, chicken, beans, eggs and processed proteins; oils, sauces and gravy; snacks such as peanuts, pretzels, potato chips; sweets; beverages such as soft drinks, juice, alcoholic beverages; and more. Each package 13 is identified with respect to the type of food it contains, preferably both in writing and optionally via an image. Moreover, the foods may be packaged and stored in varying conditions, according to the method of storage and desired preparation method. For example, foods may be packaged after mixing, precooking, freezing, dehydrating, freeze-drying or otherwise treating them for purposes of preservation. Preferably, such foods have a sufficiently long storage or shelf-life that they may be packaged well in advance of consumption. For some foods it is known that storage or shelf-life under retail conditions ranges between nine to twelve months.

The gist of the present invention is that the foods, irrespective of their type or nature, are packaged in quantities having a predetermined and substantially uniform content of at least one nutritional component. The nutritional component being controlled or limited may be almost any food component and will be different according to the purpose for which the food is being consumed. For example, the nutritional component controlled may be calories when method 10 is employed for weight control purposes, or may be vitamins, minerals or other micronutrients when method 10 is used for nutritional enhancement or fortification, or may be sugar, sodium, cholesterol, fats or saturated fats if method 10 is part of a disease treatment or prevention program. The nutritional component controlled by method 10 may also be carbohydrates, proteins, amino acids or any other component that is common to the various foods. Each package is preferably identified with respect to the predetermined content of the nutritional component it contains. Moreover, each package preferably contains an indication of the availability of different types of food having the same predetermined content of the nutritional component.

Packages of food, each having packaged therein a type of food in a quantity having a predetermined content of at least one nutritional component is hereinafter referred to herein as food units.

Because the nutritional component being controlled may vary, method 10 is useful for a number of different purposes. For example, method 10 may be employed for purposes of weight control by assisting dieters to comply with a predetermined daily caloric intake. According to this example, food products will be packaged in quantities containing a substantially uniform number of calories. Method 10 may also be employed to implement a dietary health management plan for preventing, treating or reducing risk factors associated with diet-responsive conditions, such as obesity or overweight; hyperlipidemia; non-insulin dependent diabetes; hypercholesterolemia; hyperglycemia and many others by supplying a diet avoiding certain nutritional components that cause or exacerbate such conditions. Method 10 may also be used for diet

enhancement/fortification by supplying a predetermined percentage of the US Recommended Dietary Allowance (USRDA) of the desired nutrients, such as carbohydrates, sugars, cholesterol, fats, fiber, proteins, amino acids, minerals and vitamins, to assure that a person meets his/her daily nutritional needs.

- 5 Method **10** is also appropriate to provide a diet that limits certain substances for those with limited tolerances by providing foods devoid of or low in certain nutritional components, such as sodium, sugar, cholesterol, saturated fat and the like.

10 A preferred embodiment of the invention is for method **10** to be used to treat obesity and overweight conditions for weight reduction, as method **10** is well suited to provide a controlled and consistent daily caloric level.

No single caloric level or range is appropriate for all persons. Therefore, in order to effectively use method **10** for this purpose, it is necessary to determine an appropriate caloric intake level. This may be determined by the
15 subject's Physician or calculated for each person individually by entering personal data into the gender specific Harris-Benedict equation, as follows: First, the person's sex, weight (W) (in kilograms), height (H) (in centimeters), and Age in years (A) are determined.

The person's activity level then is determined from the following scale.

20	Very light	1.3	(about 10 hours rest, about 14 hours of very light activity)
25	Light	1.5	(sedentary job, minimal leisure time activity)
	Light-moderate	1.625	(sedentary job, about 2-3 hours regular leisure-time activity/week)
30	Moderate	1.75	(sedentary job, > about 3 hours

15

regular leisure-time
activity/week)

5 Strenuous 2.0 (regular leisure-time
activity/week)

Very Strenuous 2.3 (light-moderate manual labor
heavy labor)

10

Second, the weight, height, age, and activity values are entered into the following gender-specific equation:

Males:

15 $[66.5 + (13.8 \times W) + (5.0 \times H) - (6.8 \times A)] \times \text{Act. Allow.}$

Females:

$[655.1 + (9.6 \times W) + (1.8 \times H) - (4.7 \times A)] \times \text{Act. Allow.}$

20

Act. Allow. = activity allowance

These equations provide the recommended daily caloric intake.

According to a preferred embodiment, method 10 provides a range of food units or packages, each containing a type of food having a predetermined content of about 100 calories. The food type in each package may vary and will preferably comprise a wide range of foods from each of the food groups. For example, each package may contain a food selected from the dairy product group and may include a serving equivalent to 100 calories of skim milk, cottage cheese, yogurt or the like. The package may contain a selection from the fruit group such as an apple, banana, orange, pear, plum, grapefruit, melon or a serving of berries cherries or grapes, each substantially equivalent to 100 calories. It may contain bread or baked goods substantially equivalent to 100

calories, or a 100 calorie equivalent portion selected from the vegetable group such as a serving of asparagus, beets, tomatoes, mushrooms, carrots, zucchini, green beans, broccoli, or the like. These vegetables may be packaged raw or cooked or combined into a serving of mixed vegetables which may include a
5 calorie controlled amount of sauce or dressing. The package may be a can or bottle containing a 100 calorie serving of a soft drink or juice. As can be seen, a wide variety of different food products, prepared in different fashions, may be selected from in order to comply with the predetermined daily calorie level.

Accordingly, a person may select from a widely varied "menu" of
10 options in selecting a daily diet. All that is needed in order to consume the correct amount of calories is to determine and count the packages consumed.

However, in order to attain proper nutrition, it is also necessary to ingest a balanced diet such that the calories are acquired from different nutritional sources. In accordance with recommendations by the National Academy of
15 Science, National Research Council and Food and Nutrition Board Subcommittee on the Recommended Dietary Allowances, diets preferably provide about 20 to 30% of calories from fat, about 15 to 20% from protein, and about 55 to 60% from carbohydrates. Therefore, food units will also indicate the type of food within the package and preferably the nutrient that the
20 food represents.

It is understood that for the purpose of easy compliance, packages may contain any uniform number of calories, such as 100 calories, multiples of 100 calories, or any number of calories that may be deemed to be easy, convenient or otherwise appropriate to aid in compliance with a limited-calorie diet.

25 A further preferred embodiment of the invention is for method 10 to be used to provide a desired amount of nutrients such as protein, carbohydrates, fats, fiber, vitamins and minerals, to fortify and enhance a diet. It is known that various combinations of macro and micronutrients are desirable to address specific needs in treating and preventing diet-responsive conditions, as well as
30 maintaining general good health. Therefore, according to method 10, food

units may be created such that the quantities in each package 13 will have a substantially uniform quantity of one or more of such nutritional components.

In particular, such food units may preferably contain vitamins and minerals for which a USRDA has been set by the U.S. food and Drug Administration or by the U.S. Department of Agriculture (USDA), such as
 5 Vitamins A, B.sub.1, B.sub.2, B.sub.3, B.sub.6, B.sub.12, C, D, E, and K, and Biotin, Calcium, Copper, Folic Acid, Iodine, Iron, Magnesium, Manganese, Pantothenic Acid, Phosphorus, and Zinc. It is understood that fortification of certain nutritional components may require approval by a governmental
 10 regulatory authority, such as the USDA.

Vitamins and minerals, for which a USRDA has been established, are identified in the following table, along with the respective amount.

U.S. Recommended Dietary Allowance (USRDA)	
NUTRIENT	USRDA
15	
VITAMIN A	5000 IU
VITAMIN B ₁	1.5 mg
VITAMIN B ₂	1.7 mg
VITAMIN B ₃	20 mg NE.sup.1
20	
VITAMIN B ₆	2 mg
VITAMIN B ₁₂	6 mcg
VITAMIN C	60 mg
VITAMIN D	400 IU
VITAMIN E	30 IU
25	
VITAMIN K	NONE ESTABLISHED
BIOTIN	300 mcg
CALCIUM	1000 mg
COPPER	2 mg
FOLIC ACID	400 mcg
30	
IODINE	150 mcg
IRON	18 mg

	MAGNESIUM	400 mg
	MANGANESE	NONE ESTABLISHED
	PANTOTHENIC ACID	10 mg
	PHOSPHORUS	1000 mg
5	ZINC	15 mg

Food units according to method 10 will preferably contain an amount that allows a subject to achieve the USRDA minimum or other designated level of consumption of any particular nutrient by eating a predetermined number of
10 food units per day. As with calories, in order to achieve the USRDA minimum of nutrients, a subject need only count the food units containing the relevant nutrient eaten each day.

A further preferred embodiment of the invention is for method 10 to be used to provide a predetermined amount of a nutritional component in order to
15 treat a diet responsive condition. Many conditions are diet responsive. Indeed, there are those who would argue that all physical conditions are diet responsive. Without arguing the validity of the assertion, suffice is to say that there are a number of conditions about which there is no argument that they are diet responsive, similar to obesity and overweight, discussed hereinbefore.

Accordingly, method 10 may preferably be used by a subject who
20 suffers from diabetes, hypercholesterolemia, hyperglycemia and other diseases and conditions. For example, a diet for both medically stabilized and non-medically stabilized diabetes is designed to control plasma glucose and plasma lipid levels and maintain body weight at a level appropriate for the
25 particular patient. Therefore, such a diet will have two components: First, the ADA has recommended that the intake of simple sugars be restricted and that complex carbohydrates be increased for diabetics; and second, the diet will include an appropriate caloric level tailored to a subject's height, weight, age, sex and activity level. Although the indicators associated with diet-responsive
30 diabetes must be specifically determined for each individual patient, a typical

1500 calorie menu prepared by the ADA holds simple sugars to within a range of about 96 to 107 grams from fruits and vegetables. Accordingly, method **10** is useful for diabetics as it can be used to control and monitor both sugar intake and calories simultaneously.

5 Subjects suffering from hypercholesterolemia or any form of hyperlipidemia are often instructed to limit fats, particularly polyunsaturated fatty acids, in order to lower total serum cholesterol, triglycerides and LDL. Subjects most likely to achieve reductions in cholesterol and triglyceride levels as a result of dietary control are those without lipid lowering medication that
10 have cholesterol levels in a range of about 220 to 300 mg/dl or triglyceride levels in a range of about 200 to 1000 mg/dl, or both, or those with lipid lowering medication that have cholesterol levels of about 200 to 260 mg/dl or triglyceride levels of about 200 to 1000 mg/dl. By using method **10**, a subject can easily control and monitor the intake of fat in the diet, which may have the
15 added benefit of reducing dependency on lipid lowering medication.

Cancer is another disease about which there is controversy regarding its responsiveness to dietary factors. However, it is acknowledged that certain dietary elements influence the progression of the disease. High dietary fiber, low fat consumption and adherence to daily recommended allowances for
20 certain vitamins and minerals, including vitamins A and C, reduce the risk factors associated with various types of cancers. Method **10** may be easily applied to both structure an appropriate diet and to easily adhere to it without cumbersome or difficult calculations by determining and consuming the correct number of the appropriate food units.

25 As illustrated above, method **10** is designed to be a highly flexible instrument for building a diet appropriate for a variety of purposes. The great variation of the food units themselves will make it easy to create an interesting and balanced diet while at the same time observing a wide range of dietary restrictions, both those avoiding or limiting certain nutrients and those in which

a predetermined quantity of certain nutrients must be eaten. Method 10 will make it almost effortless and foolproof to observe all such requirements.

Method 10 may also preferably provide guidance with respect to proper adherence to dietary guidelines. For this purpose, each food unit may preferably contain an indication of the nature of method 10 and its implementation. In this connection, each package 13 may preferably contain an indication of different foods that are similarly packaged, each one containing the predetermined and substantially uniform content of at least one nutritional component. Each package 13 may also preferably contain a list of different foods being packaged such that each one contains the predetermined content of a number of nutritional components. Such food units with multiple nutrient content may be created in different combinations designed to address specific diet responsive conditions or to meet the needs of subjects with specific dietary or nutritional requirements, with each food unit containing an indication of how its contents may be part of a balanced diet focused toward achieving a nutritional goal by implementing method 10.

Method 10 may also preferably be used to closely monitor the food intake of a subject and to accurately document the food units consumed. Method 10 is particularly designed for carrying out such precise record keeping in an easy and convenient manner.

The purpose of monitoring nutritional intake may vary, and therefore method 10 is useful for a number of purposes. For example, strict adherence to a diet may be essential for treatment of a health condition; a subject may wish to monitor intake in order to understand the relationship between food intake and weight gain or loss; diet restriction may be needed to study the relationship between intake of various food components and related physiological conditions, including the influence of certain substances; limited or restricted food intake may be an aspect of scientific or statistical research, requiring close observation; and there may be additional reasons why a diet must be carefully monitored or controlled.

It is a feature of method 10 to facilitate the documentation by the dieter of the nutritional components consumed. Whereas other food packaging methods and configurations may provide a range of nutritional information, some of which is required by law, method 10 not only provides information to the dieter, but also provides an easy and foolproof way to accurately document that information. It is understood that such documentation may be medically required for accurate follow-up of disease treatment or for other purposes. Such documentation may also be used simply to assist a dieter to learn his/her actual nutritional needs and to incorporate appropriate eating habits into daily life.

Reference is made to Figure 3 in which package 13 is shown containing a marker 14 having thereon an indication in print identifying the type of food contained therein, hereinafter referred to as indication 15 and indicating the predetermined content of its designated nutritional component or components, hereinafter referred to as indication 16. In addition, each marker 14 may also preferably have other useful information, such as an indication of the availability of a plurality of different types of food having the same predetermined content of nutritional component, hereinafter referred to as indication 17, or an indication of the method of using the plurality of different types of food to form a personal daily nutritional intake, hereinafter referred to as indication 18.

Marker 14 may be of many different types, attached on or inserted in each package 12. It is a feature of marker 14 that indications 15 and 16 be removable and reattachable such that these indications may be easily removed from package 13 and recorded in a recording device.

Reference is made to Figure 4 which shows a recording device 30 in accordance with a preferred embodiment of the present invention. Recording device 30 is shown as a daily diary with pages having spaces on which information relevant to food intake may be entered. It is understood that recording device 30 may also take the form of a calendar, a loose-leaf binder and pages or any other device for orderly retention of information.

One of the purposes of method **10** is to monitor intake. Accordingly, in order to document the adherence to a nutritional regimen by creating a contemporaneous record of the nutritional intake, a subject merely has to transfer indications **15** and **16** from package **13** to recording device **30** which
5 records it at the time of eating the contents of the package. One way such a transfer may be effected is by marker **14** itself being removable and reattachable in recording device **30** configured as a daily diary, with spaces provided for the requisite number of markers **14** each day. Alternately, marker **14** could contain thereon a removably affixable label **19**, which contains a one
10 use adhesive permitting it to be stuck onto a page in recording device **30** configured as a daily record in either book or calendar form. Other alternative documentation methods may be employed so long as they permit the recording of the information on the package along with the consumption of the food within the package. Such methods may consist of adhesive stickers with printed
15 information, graphics, symbols or any identifiable indication. Additionally, such stickers may be used for the purpose of documenting non-nutritional elements related to the subject, such as exercise, daily activities and the like in order to create a more complete or comprehensive daily record of the factors affecting a subject's health. A further documentation method may employ a
20 coded reference which appears on marker **14** or on package **13** in a machine readable code such as a bar code which can be read and decoded by an optical reader which transmits to recording device **30** configured as an electronic database. A subject could simply scan the coded reference immediately prior to opening package **13** in order to effortlessly create a precise and accurate
25 contemporaneous record of the nutrition consumed each day, including the time of consumption of each food unit. Such codes, optical readers and electronic databases are well known in the art and therefore neither a more detailed description nor an explanation is required herein.

It is understood that recording device **30** will preferably be used while
30 implementing method **10** and will therefore be designed and configured to

assist a dieter to conform to the requirements of method 10. Accordingly, recording device 30 may preferably contain useful information such as an indication of the availability of a plurality of different foods being packaged such that each one contains the same predetermined content of nutritional components.

It is envisioned that an extremely wide variety of food units may be provided within the scope of method 10, each one being identified as one of an assembly of food units comprising a plurality of food units. Each food unit of the assembly of food units will have a package marked in a specific manner that identifies it as part of the assembly and capable of being combined with other food units having similarly marked packages to form a diet of personal daily nutrition that may be directed toward one or more dietary purposes. The distinctive marking that so identifies each food unit may be of any type, such as printing, graphics, symbols, color scheme, type or shape of the package or any manner of distinctive marking such that the package bears the visible identity of the assembly of which it forms a part. Such distinctive marking may preferably constitute a registered mark or "brand" for the purpose of protecting the producer/manufacturer and to promote consumer recognition.

Reference is made to Figures 5a and b. It is the intent of the invention to create an assembly of food units, hereinafter referred to as assembly 20, comprising a plurality of food units, each containing a different type of food packaged in package 13 in a portion substantially uniform to other packaged portions in content of at least one nutritional component. The assembly will constitute a line of food products, all with similar visually identifying characteristics that will share a nutritional characteristic, such as, for example, each package 13 containing substantially 100 calories.

To further create assembly 20, the plurality of food units will be packaged in a container, shown as 21 in Figure 5a, or displayed on a presentation stand preferably designed and configured as display 23 in figure 5b, further indicating their common identity and usage. In order to further

assure the association of method 10 with assembly 20, container 21 and display 23 both have similar visual characteristics and preferably contain markers 22 having the same indications that appear on each package 13, specifically indication 15 showing the nature or type of food contained in each package and indication 16 showing the predetermined content of the nutritional component or components., and may also preferably contain indication 17 showing the availability of a plurality of different types of food having substantially the same nutritional component and indication 18 describing method 10 and how to use the food units to achieve a desired diet.

Consumers will know by the common distinctive marking of package 13, container 21 and of display 23 that each food unit contained therein or displayed thereon shares a common characteristic, for example, a caloric content of 100. Such common visual characteristics may serve as, or may be adopted by a producer\manufacturer as a marketing "brand" which serves to identify all of the food units sharing the common characteristic.

It is easy to visualize that assembly 20 may be set up to create a food marketing chain such as a series of convenience stores or a discrete marketing unit such as a store within a store. For example, a marketing chain such as a supermarket could create a section containing a number of assemblies 20, each visually identified with common identifying markings and each with its own nutritional characteristic, such as calorie content 100, calorie content 100/no fat, calorie content 100/low sodium, calorie content 100/vitamin B fortified, and many more. The consumer will come to recognize the "brand", or displayed appearance of assembly 20 and will associate it with method 10, understanding that he needs simply to take and eat the correct number of food units each day to achieve the desired content of personal daily nutrition.

Method 10 provides a number of advantages over existing methods of diet building, monitoring and compliance, as follows:

1. Method 10 eliminates the difficulty in counting calories, especially as most people are unaware of the caloric content of their foods. Method 10 provides a precise and reliable method of monitoring daily calories.

2. Most diets consist of a number of different elements that define the diet, for example length of the diet, how many meals per day, primary foods, and more. Method 10 is flexible and can be adapted to any of such diet requirements.

3. Method 10 teaches, in the most effective way, the issue of portion control, a critical element of every diet and for maintaining a healthy lifestyle.

4. Method 10 includes a wide variety of foods, unlike diets that are based upon prepared foods only. A consumer can choose between hot food and cold food, prepared food or ingredients, between a meal or a snack, and more. Since most people are reluctant to give up the pleasures of life, meaning the tasty food in their menu, method 10 allows a consumer to eat any food even though it may not be defined as dietetic. This flexibility will allow a dieter to build a daily menu that is pleasing and will, therefore, aid in compliance.

5. Method 10 is not based on the statistical average consumer but on a personal and customized approach for each consumer. By using method 10, anyone can learn his caloric balance point, the daily caloric intake needed to maintain weight. Also, anyone can learn from personal experience whether the amount of calories consumed is the only factor contributing to the maintenance of weight or whether maintenance of weight is related to other factors, such as the types or components of food, physical activity, etc. This examination will allow a consumer to learn healthy eating and other lifestyle habits.

6. The wide variety of foods included within method 10 will allow a marketing chain to create a recognized and attractive product with an identifiable brand, having a variable price to the consumer. "Recognition buying" is known to be a powerful commercial force.

Moreover, method **10** provides an effective way to lose weight. According to the FDA, there are three principles of a successful weight control program;

1. to either reduce the number of calories consumed or to increase
5 the number of calories burned by increasing physical exercise;
2. to avoid sudden or radical changes in eating patterns which will be difficult to sustain; and
3. to make long term changes in daily eating and exercise habits.

Method **10** positively addresses each of the above principles by both
10 teaching the concept of portion control and facilitating the learning of the caloric content of foods eaten. The adoption of method **10** will result in the dieter gaining an understanding of the effect that the desired foods have on his/her body weight and the importance of moderation in the daily consumption of food. This understanding will be gained passively and effortlessly via
15 personal experience and observation and not from laborious study or memorization of charts or tables and will therefore provide a basis for continued adherence to healthy eating habits.

It is appreciated that certain features of the invention, which are, for
20 clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

25

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention is defined by the appended claims and includes both combinations and subcombinations of the
30 various features described hereinabove as well as variations and modifications

thereof which would occur to persons skilled in the art upon reading the foregoing description. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

WHAT IS CLAIMED IS:

1. A method of monitoring or controlling a nutritional intake of a subject, the method comprising:

- (a) providing a plurality of food packages, said plurality of food packages containing a plurality of different types of foods, each of said plurality of different types of foods having a predetermined and substantially uniform content of at least one nutritional component; and
- (b) monitoring or controlling a number of said plurality of food packages consumed by the subject per eating session or per a predetermined time period;

thereby monitoring or controlling the nutritional intake of the subject

2. The method of claim 1, wherein each of said plurality of food packages is identified with respect to a type of food it contains.

3. The method of claim 1, wherein each of said plurality of food packages is identified with respect to a content of said nutritional component it contains.

4. The method of claim 1, wherein each of said plurality of food packages contains an indication of the availability of a plurality of different types of foods having said predetermined content of at least one nutritional component.

5. The method of claim 1, wherein each of said plurality of food packages contains an indication of said method.

6. The method of claim 1, wherein said at least one nutritional component is selected from the group consisting of carbohydrates, sugars, fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

7. The method of claim 1, wherein said at least one nutritional component is calorie content.

8. The method of claim 7, wherein said calorie content is selected from the group consisting of about 50 calories, about 75 calories, about 100 calories, about 125 calories, about 150 calories, about 175 calories, about 200 calories, about 225 calories, about 250 calories, about 275 calories and about 300 calories.

9. The method of claim 7, wherein said calorie content is about 100 calories.

10. The method of claim 1, wherein the subject has a diet-responsive condition.

11. The method of claim 1, wherein said diet-responsive condition is selected from the group consisting of obesity, overweight, diabetes, hypercholesterolemia and hyperglycemia.

12. The method of claim 1, wherein said foods are selected from the group consisting of natural foods, processed foods and drinks.

13. The method of claim 1, wherein said foods are processed to extend shelf life.

14. The method of claim 1, wherein each of said packages is marked in a specific manner that identifies it with an assembly which comprises similarly marked packages.

15. The method of claim 1, wherein each of said plurality of food packages contains a marker which provides information about said at least one nutritional component.

16. The method of claim 15, wherein said marker is or includes a removably affixable label.

17. The method of claim 15, further comprising recording said information about said at least one nutritional component in a recording device.

18. The method of claim 17, wherein said recording device is a diary or a calendar, said marker being affixable thereto.

19. The method of claim 1, wherein the subject participates in a nutritional research.

20. The method of claim 1, wherein said plurality of food packages is prepackaged in a container.

21. The method of claim 1, wherein said plurality of food packages is displayed on a display.

22. The method of claim 1, wherein said time period is one day.

23. A food unit comprising:

(a) a package;

- (b) a type of food packaged in said package and having a predetermined content of at least one nutritional component;
- (c) an indication in print on or in said package, said indication indicating:
 - (i) the predetermined content of said at least one nutritional component; and
 - (ii) an availability of other food units of a plurality of different types of foods, each of said plurality of different types of foods having said predetermined content of at least one nutritional component.

24. The food unit of claim 23, wherein said indication further indicates a method of monitoring or controlling a nutritional intake of a subject via monitoring or controlling a number of food units consumed by the subject per eating session or per a predetermined time period.

25. The food unit of claim 24, wherein said predetermined time period is one day.

26. The food unit of claim 23, wherein said type of food is selected from the group consisting of natural foods, processed foods and drinks.

27. The food unit of claim 23, wherein said type of food is processed to extend shelf life.

28. The food unit of claim 23, wherein said type of food is for consumption by a subject seeking to control calorie intake.

29. The food unit of claim 23, wherein said type of food is for consumption by a subject having a diet-responsive condition.

30. The food unit of claim 29, wherein said diet-responsive condition is selected from the group consisting of obesity, overweight, diabetes, hypercholesterolemia and hyperglycemia.

31. The food unit of claim 23, wherein said at least one nutritional component is selected from the group consisting of carbohydrates, sugars, fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

32. The food unit of claim 23, wherein said at least one nutritional component is calorie content.

33. The food unit of claim 32, wherein said calorie content is selected from the group consisting of about 50 calories, about 75 calories, about 100 calories, about 125 calories, about 150 calories, about 175 calories, about 200 calories, about 225 calories, about 250 calories, about 275 calories and about 300 calories.

34. The food unit of claim 32, wherein said calorie content is about 100 calories.

35. The food unit of claim 23, wherein said indication is located on a marker.

36. The food unit of claim 35, wherein said marker is or includes a removably affixable label.

37. The food unit of claim 23, wherein said food unit is prepackaged in a container.

38. The food unit of claim 23, wherein said plurality of food packages is displayed on a display.

39. A food unit comprising:

- (a) a package;
- (b) a type of food packaged in said package and having a predetermined content of at least one nutritional component; and
- (c) a removably affixable label on or in said package indicating thereon the predetermined content of said at least one nutritional component.

40. The food unit of claim 39, wherein said type of food is selected from the group consisting of natural foods, processed foods and drinks.

41. The food unit of claim 39, wherein said at least one nutritional component is selected from the group consisting of carbohydrates, sugars, fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

42. The food unit of claim 39, wherein said food unit is prepackaged in a container.

43. The food unit of claim 39, wherein said plurality of food packages is displayed on a display.

44. A system for monitoring or controlling a nutritional intake of a subject, the system comprising:

- (a) at least one package;
- (b) a type of food packaged in said at least one package and having a predetermined content of at least one nutritional component, said at least one package having therein or thereon information about said predetermined content of said at least one nutritional component; and
- (c) a recording device for recording said information about said predetermined content of said at least one nutritional component

such that said information on said package may be recorded in said recording device, thereby to monitor or control a nutritional intake of a subject.

45. The system of claim 44, wherein said at least one nutritional component is selected from the group consisting of calories, carbohydrates, sugars, fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

46. The system of claim 44, wherein said package further has therein or thereon information about said type of food.

47. The system of claim 44, wherein said type of food is selected from the group consisting of natural foods, processed foods and drinks.

48. The system of claim 44, wherein said information is contained on a marker in or on said package.

49. The system of claim 48, wherein said marker is or includes a removably affixable label.

50. The system of claim 49, wherein said recording device is a diary or a calendar, said removably affixable label being affixable thereto.

51. An assembly of food units comprising a plurality of food units, each of said food units comprising:

- (a) a package; and
- (b) a different type of food packaged in said package and having a predetermined content of at least one nutritional component, said predetermined content of said at least one nutritional component is substantially uniform for all of said plurality of food units of said assembly of food units.

52. The assembly of claim 51, further comprising an indication in print, said indication indicating the predetermined content of said at least one nutritional component.

53. The assembly of claim 52, wherein said indication further indicates the nature of the food contained in each said package.

54. The assembly of claim 52, wherein said indication further indicates the availability of a plurality of different types of foods having said predetermined content of at least one nutritional component.

55. The assembly of claim 52, wherein said indication further indicates a method of monitoring or controlling a nutritional intake of a subject via monitoring or controlling a number of food units consumed by the subject per eating session or per a predetermined time period.

56. The assembly of claim 52, wherein said indication is located on a marker.

57. The assembly of claim 56, wherein said marker is or includes a removably affixable label.

58. The assembly of claim 51, wherein said plurality of food units of said assembly are packaged in a container.

59. The assembly of claim 58, wherein said container comprises therein or thereon an indication in print, said indication indicating the predetermined content of said at least one nutritional component.

60. The assembly of claim 59, wherein said indication further indicates the nature of the food.

61. The assembly of claim 59, wherein said indication further indicates the availability of a plurality of different types of foods having said predetermined content of said at least one nutritional component.

62. The assembly of claim 59, wherein said indication further indicates a method of monitoring or controlling a nutritional intake of a subject via monitoring or controlling a number of food units consumed by the subject per eating session or per a predetermined time period.

63. The assembly of claim 51, wherein said plurality of food units of said assembly are displayed on a display.

64. The assembly of claim 63, wherein said display comprises an indication in print, said indication indicating the predetermined content of said at least one nutritional component.

65. The assembly of claim 64, wherein said indication further indicates the nature of the food contained in said package.

66. The assembly of claim 64, wherein said indication further indicates the availability of a plurality of different types of foods having said predetermined content of at least one nutritional component.

67. The assembly of claim 64, wherein said indication further indicates a method of monitoring or controlling a nutritional intake of a subject via monitoring or controlling a number of food units consumed by the subject per eating session or per a predetermined time period.

68. The assembly of claim 51, wherein said at least one nutritional component is selected from the group consisting of carbohydrates, sugars, fats, cholesterol, fiber, proteins, amino acids, minerals and vitamins.

69. The assembly of claim 51, wherein said at least one nutritional component is calorie content.

70. The assembly of claim 69, wherein said calorie content is selected from the group consisting of about 50 calories, about 75 calories, about 100 calories, about 125 calories, about 150 calories, about 175 calories, about 200 calories, about 225 calories, about 250 calories, about 275 calories and about 300 calories.

71. The assembly of claim 69, wherein said calorie content is about 100 calories.

72. The assembly of claim 51, wherein said food is selected from the group consisting of natural foods, processed foods and drinks.

73. The assembly of claim 51, wherein said food is processed to extend shelf life.

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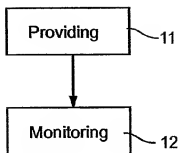
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Fig. 1

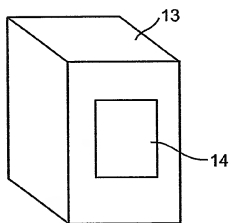


Fig. 2

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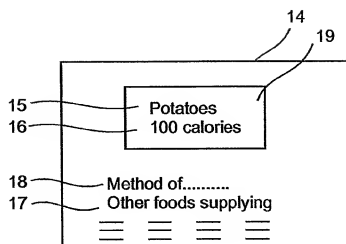


Fig. 3

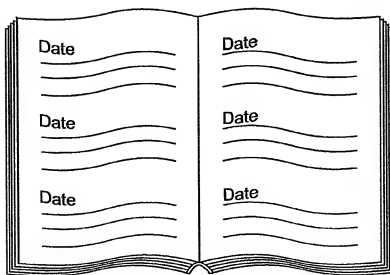
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Fig. 4

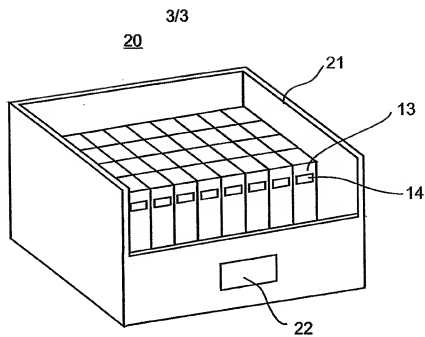


Fig. 5a

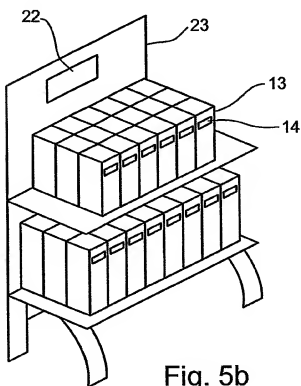


Fig. 5b